REMARKS/ARGUMENTS

Applicant and Applicant's attorney express appreciation to the Examiner for the courtesies extended during the recent interview held on July 29, 2004. Reconsideration and allowance of the above-identified application are now respectfully requested.

Claims 1-18, 20, 21 and 23-34 are pending, wherein claims 1, 17, 21, 24, 25 and 29 have been amended and new claims 33 and 34 have been added.

I. INTRODUCTION

The present application discloses soft tissue interference screws that are designed to provide fixation of a soft tissue graft against both cortical and cancellous bone tissue found within a bone tunnel. Interference screws generally work by pushing one or more strands of a soft tissue graft against the bone tunnel wall. In the short term, interference screw fixation needs to be strong enough to firmly hold the soft tissue graft in place and prevent pull-out or substantial loosening of the graft before the graft and bone have had a chance to heal and grow together. In the long run, it is advantageous for the soft tissue graft to fuse together with the bone tissue to form a permanent living tissue graft. Once substantial fusion of the soft tissue graft and bone tissue have occurred the interference screw becomes largely superfluous.

One of the challenges of interference fixation is providing an interference screw that is able to exert sufficient force to provide strong initial fixation of the soft tissue graft, but not so much force that it causes long-term damage to, and potential weakening of, the soft tissue graft. The amount of force that is applied by an interference screw against a soft tissue graft is related to the diameter of the screw relative to the diameters of the bone tunnel and soft tissue graft, as well as the relative hardness of the bone and/or the stiffness of the soft tissue graft. Because of variability in bone hardness among patients, as well as variability in the thickness and/or stiffness of soft tissue strands between different persons, designing an interference screw that is able to strike the correct balance between providing strong initial fixation, on the one hand, and preventing undo damage to the soft tissue graft, on the other, has proven to be quite difficult. Accordingly, there is a need, long-felt in the art, to provide interference screws and methods able to provide strong initial fixation while also preventing undo damage to the soft tissue graft.

One proposed solution is to provide a pair of short interference screws that are placed at each end of the bone tunnel in order to provide bicortical fixation, *i.e.*, U.S. Patent No. 6,387,129 to Rieser et al. According to this method, an initial fixation force is applied by each interference

screw in the hard cortical bone region at either end of the bone tunnel. One disadvantage of this fixation system is the practical difficulty in placing the fixation screw at the back of the bone tunnel after first drawing the soft tissue graft through the bone tunnel (*i.e.*, the screw closest the joint must be placed deeply enough to firmly engage cortical bone but not so deeply as to extend beyond the bone tunnel and scrape against the cartilage of the joint.

The interference screws and methods disclosed in the present application have proven to be capable of striking the correct balance between strong initial fixation of the soft tissue graft while preventing undo damage to the soft tissue graft. The inventive interference screws provide strong initial fixation of the soft tissue graft by having a length sufficient to provide both cortical and cancellous bone fixation of the soft tissue graft. Moreover, the increased diameter of the inventive interference screws in the cortical bone region of the bone tunnel provides even greater initial fixation of the soft tissue graft. Conversely, the reduced diameter of the inventive interference screws in the cancellous bone region of the bone tunnel prevents undo damage to the soft tissue graft. According to one embodiment, the length of the interference screw is such that it extends through a majority of the bone tunnel. Because the cancellous bone region is much thicker than the cortical bone region, preferred interference screws provide more gentle fixation along a majority of the interference screw in the larger, but softer, cancellous bone region, while limiting the strongest fixation to the smaller, but harder, cortical bone region.

II. RESPONSE TO CLAIM REJECTIONS

The Office Action rejects claims 1-18, 20-21, 23-24, 28-29, 31 and 32 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 2,382,019 to Miller in view of Rieser et al.; claim 25 over U.S. Patent No. 6,368,322 to Luks et al. in view of U.S. Patent No. 6,565,566 to Wagner et al.; and claims 26, 27 and 30 over Miller in view of Rieser et al. and Wagner et al.[1] In response, Applicant has amended the independent claims in a manner that is believed to distinguish over the art of record. Applicant also believes that one of skill in the art would not have been motivated to combine the teachings of Miller and Rieser et al. or Luks et al. and Wagner et al.

[1] Because Rieser et al., Luks et al., and Wagner et al. are only citable under 35 U.S.C. § 102(e), Applicant does not admit that these references are in fact prior art but reserves the right to "swear behind" one or more of Rieser et al., Luks et al., and Wagner et al. in order to remove them as a reference.

A. **The Combination of Miller and Rieser et al.**

Applicant believes that one of skill in the art would not have been motivated to combine Miller and Rieser et al. because each reference discloses a solution to a fundamentally different technical problem. In addition, each reference discloses structural features that are necessary for the disclosed device to operate as intended, and modifying one device according to the teachings of the other reference would render the modified device unsatisfactory for its intended purpose. Finally, Miller is nonanalogous to both Rieser et al. and the present invention. As a result of any of the foregoing, the Office Action fails to state a *prima facie* case of obviousness relative to claims 1-18, 20-21, 23-24 and 26-32.

The technical problem solved by Miller is to provide a screw that is able to be driven into "unbored wooden material" (*i.e.*, wood having no hole pre-drilled therein). Col. 1, line 50 – col. 2, line 12. On the other hand, the technical problem solved by Rieser et al. is to provide means for providing bicortical fixation of an anterior cruciate ligament graft within a pre-drilled bone tunnel. Col. 1, lines 12-15 and 54-57. One of skill in the art would not have been motivated to modify the Miller screw according to Rieser et al. because doing so would not be expected to provide an enhanced solution to the problem of driving a screw into unbored wood. The fact that the Rieser et al. screw is designed to be inserted into a pre-drilled bone tunnel would lead one of skill in the art away from modifying the Miller screw according to Rieser et al. since doing so would be reasonably be expected to make the Miller screw *less able* to be driven into unbored wood or material, not more able. On the other hand, assuming for the moment that Rieser et al. were cited as the primary reference, one of skill in the art would not have been motivated to modify the Rieser et al. screw according to Miller. The fact that the Miller screw is designed with an elongated point (and preferably a head) in order to initially drive the screw into "unbored wooden material . . . by means of hammer blows, or the like, until the thread 5 begins to enter the wood" (col. 1, lines 50-55), one of skill in the art would not have been motivated to modify the Rieser et al. screw since doing so would not reasonably be expected to enhance bicortical fixation within a pre-drilled bone tunnel.

Moreover, one of skill in the art would not have been motivated to modify the Miller screw according to Rieser et al. because any such modification would render the Miller screw unsatisfactory for its intended purpose. According to MPEP § 2143.01, "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification" (citing *In*

re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)). According to the Office Action, "it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the [Miller] screw with an angled proximal end, as taught by [Rieser et al.], so that the [Miller] screw would be flush with the outer surface of the bone in which it is placed." Office Action, pp. 2-3. The Office Action further asserts that it would have been obvious "to have provided the proximal end of the [Miller] with an angle within a range of 10 to 80 degrees". *Id.* at p. 3.

The problem with modifying the Miller screw to have an angled proximal end is that it would render the Miller screw unsatisfactory for its intended purpose (*i.e.*, being able to be "hammered, or the like" into "unbored wooden material"). It is well-known to anyone who has ever attempted to hammer a nail or screw into a board that the failure to strike the nail exactly straight down on the top of the head (*i.e.*, perpendicular to the longitudinal axis of the nail or screw) causes the nail to bend or the screw to lay down flat or fly off to the side. Providing a nail or screw with an angled proximal end would greatly exacerbate the tendency of the nail or screw to bend, lay down flat, or fly off to the side. Modifying the Miller screw to have an angled proximal end would create a camming surface able to convert some of the downward force of the hammer blows into a transverse force approximately normal to the angled proximal end. The transverse force acting on the proximal end of the modified Miller screw would be superficially much greater than any offsetting forces at the distal end of the Miller screw, which only superficially touches the "unbored wooden material" initially before being driven into the unbored wood. The result is that modifying the Miller screw to have an angled proximal end, particularly an angle of up to 80 degrees, would make it very difficult, if not impossible, to successfully hammer the modified screw into unbored wood. According to MPEP § 2143.01, it would not have been obvious as a matter of law to modify Miller according to Rieser et al. to have an angled proximal end because to do so would render the Miller screw unsatisfactory for its intended purpose of being able to be initially hammered into "unbored wooden material".

Not only is Miller inherently incompatible with the teachings of Rieser et al., Miller is so far outside the field of Applicant's endeavor, and so impertinent to the particular problem Applicant is trying to solve as to constitute non-analogous art. According to MPEP § 2141.01(a), "'[i]n order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.'" (Quoting *In re*

Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed Cir. 1992)). In *In re Oetiker*, the Federal Circuit reversed the Board's initial finding that hook and eye fasteners used in garments were similar, and therefore analogous, to hooks used in the claimed hose clamp assembly.

> The [Federal Circuit] held the reference was not within the field of applicant's endeavor, and was not reasonably pertinent to the particular problem with which the inventor was concerned because it had not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments.

MPEP § 2141.01(a) (under the subheading "ANALOGY IN THE MECHANICAL ARTS").

Applying MPEP § 2141.01(a) and *In re Oetiker* to the present case, it is clear that the Miller screw, which is specifically designed so as to be capable of being driven into "unbored wooden material" by "hammer blows, or the like", is not in the same field or endeavor as the present invention, which is concerned with solving the technical problem of providing strong initial fixation of a soft tissue graft while preventing undo damage to the soft tissue graft. Like clothing hooks, which were held to be nonanalogous to hose hooks in *In re Oetiker* because they provide completely different solutions to different problems, the Miller screw is nonanalogous to the inventive interference screws because they provide completely different solutions to different problems. All screws have superficial similarities in that they all have threads, proximal ends, and distal ends. However, there are many different screws that provide a myriad of different functions, with some screws being entirely unsuitable for use in place of other screws due to differences in length, diameter, thread pitch, thread depth, etc. Failure to select the one correct screw from among the thousands of available screws can result in the inability to complete the project at hand. Such is the case here. Whatever superficial similarities may exist between the Miller screw and the inventive interference screws, even minor differences between their length, diameter, thread pitch, or thread depth can render them completely unsatisfactory for their intended purpose.

In short, Miller is nonanalogous art and may not be cited against the claims in the present application. Because Miller is both nonanalogous art and the main primary reference cited in the Office Action, it is Applicant's position that the Office Action fails to state a *prima facie* case of obviousness for this reason alone, at least with respect to claims 1-18, 20-21, 23-24 and 26-32. Moreover, because one of skill in the art would not have been motivated to combine Miller with

Rieser et al., since they are incompatible, contradictory and provide entirely different solutions to different technical problems, the Office Action fails to state a *prima facie* case of obviousness relative to 1-18, 20-21, 23-24 and 26-32 for this additional reason.

B. The Combination of Luks et al. and Wagner et al.

Applicant believes that one of skill in the art would not have been motivated to combine Luks et al. and Wagner et al. because each reference discloses a solution to a fundamentally different technical problem. In addition, each reference discloses structural features that are necessary for the disclosed device to operate as intended, and modifying one device according to the teachings of the other reference would render the modified device unsatisfactory for its intended purpose. As a result, the Office Action fails to state a *prima facie* case of obviousness relative to method claim 25.

The technical problem solved by Luks et al. is to provide an interference screw that overcomes problems created by the use of metal screws. According to Luks et al., "[t]he use of metal screws, however, sometimes necessitates surgical procedures for screw removal. Moreover, metal screws have a tendency to loosen and/or back out of a previously formed bore and result in bone loss". Col. 1, lines 23-27. The solution to the problem of using metal screws, according to Luks et al., is the use of "surgical interference screws constructed from bone". Col. 1, lines 13-14. "By constructing the screw from bone, several advantages are achieved. For example, bone resorbs by biological remodeling, not by chemical means. As such, bone is replaced by bone as it resorbs". Col. 2, lines 47-50. "Moreover, bone bonds to bone. The fixation of the interference screw is enhanced as bone grows directly on to the surface of the interference screw". Col. 2, lines 52-55. "Fixation of the interference screw is enhanced by a biological bond, while metal and polymer screws must depend only on a mechanical interlock with bone". Col. 2, lines 56-58 (emphasis added). It is clear that Luks et al. teaches away from the use of metal screws.

Wagner et al. discloses "a sacral screw used during procedures for stabilizing a human spine". Col. 1, lines 9-10. Thus, instead of fixing a soft tissue graft within a bone tunnel as in Luks et al., the sacral screw of Wagner et al. is used to secure a metal spinal rod affixed to a person's spine. Col. 3, lines 10-28. Because the sacral screw of Wagner et al. is required to support heavy loads, it cannot be made from bone, which according to Luks et al. have "a tendency to split or fracture at the interface with the driver tool". Col. 1, lines 48-50. Clearly, if

a screw made of bone easily splits or fractures at the interference with the driver tool, it would likewise fracture if modified so as to function as a sacral screw used to hold a metal rod in place against a person's spine. Because of these critical differences, the teachings of Luks et al. and Wagner et al. are not properly combinable. The problem being solved in Luks et al. is so fundamentally different than the problem solved in Wagner et al. that one of skill in the art would not combine the reference under any circumstances, let alone in the manner urged the Office Action (*i.e.*, that altering the screw of Luks et al. to be more like the screw in Wagner et al. is "a matter of obvious design choice to one of ordinary skill in the art"). Because the Wagner et al. screw is designed for a completely different purpose, the features contained in Wagner et al. are not in any way "a matter of obvious design choice" relative to the bone screw of Luks et al.

Moreover, whereas Luks et al. disparages the use of metal screws, Wagner et al. specifically teaches the use of metal in manufacturing the sacral screw. "The components of the sacral screw assembly 20 may be made of steel (*e.g.*, stainless steel), steel alloys, titanium, or titanium alloys. These materials are generally non-toxic, biocompatible, strong, and non-corrosive. Other materials that have these properties may also be used." Col. 4, lines 4-9 (emphasis added). Because Luks et al. teaches the importance of utilizing bone in manufacturing the interference screw, whereas Wagner et al. discloses the importance of using steel, titanium, titanium alloys, or other materials having the same properties, modifying Luks at al. according to Wagner et al. would so alter the Luks et al. screw as to render it "unsatisfactory for its intended purpose". *See* MPEP § 2143.01.

Finally, another technical problem solved by the Luks et al. device is overcoming the "tendency [of screws made from bone] to split or fracture at the interface with the driver tool". Col. 1, lines 49-50. The solution to this problem is to provide a bore that extends along a substantial portion of the elongated body of the interference screw. *See* Col. 2, lines 4-9 ["the insertion tool engaging structure extends within the bore along a substantial portion of the length of the elongated body" (emphasis added). This is seen more clearly in Figures 4, 8 and 12 of Luks et al. In contrast, the sacral screw of Wagner includes a head 32 that is used both for fixation of the sacral screw within the patient's vertebra, as well as forming the structure for attaching a spinal rod thereto. Col. 5, lines 16-25. Because of the criticality of including an insertion tool engaging structure along a substantial portion of the length of the Luks et al. screw, but whereas such feature is necessarily omitted in order for the sacral screw of Wagner et al. to

function as intended, such fundamental differences further lead one of skill in the art away from combining Luks et al. with Wagner et al. In view of the foregoing, Applicant believes that the Office Action fails to state a *prima facie* case of obviousness relative to claim 25.

C. **The Claims Distinguish Over the Art**

In addition to the foregoing, each of the independent claims further includes limitations which distinguish over the cited art, even if combined. For example, claim 25 recites "[a] method of securing a soft tissue graft against both cortical and cancellous bone tissue within a bone tunnel". Claim 25 further recites the act of using an interference screw that is able "to apply a greater compressive force against the soft tissue graft in the cortical bone region of the bone tunnel and a lesser compressive force against the soft tissue graft in the cancellous bone region". Luks, et al., neither teaches nor suggests any such method. Nor does the Examiner even allege that Luks et al. inherently discloses a method of securing a soft tissue graft against "both cortical and cancellous bone tissue", let alone so that greater force is applied in the cortical bone region than in the cancellous bone region.

Whereas Luks et al. discloses an interference screw made of bone used to affix a soft tissue graft within a bone tunnel, there is no teaching or suggestion in Luks et al. for inserting the interference screw made from bone into a bone tunnel in such a way so as "to apply a greater compressive force against the soft tissue graft in the cortical bone region of the bone tunnel and a lesser compressive force against the soft tissue graft in the cancellous bone region". In fact, there is no indication that the interference screw in Luks et al. engages cortical bone at all when used as intended. Indeed, because none of the embodiments in Luks et al. have an angled proximal end (*see* Figures 1-12), it is highly likely that the practitioner would insert the screw far enough into the bone tunnel so as to avoid leaving any of the bone screw emerging from the bone tunnel. In the case of an angled bone tunnel, that would mean that some or all of the bone tunnel in the cortical bone region would be devoid of the interference screw. Inherency can only be established where the alleged inherent feature necessarily follows, not where it might possibly or even probably follow. *See* MPEP §2112. In any event, it is the Examiner's burden to show that Luks et al. inherently discloses the method recited in claim 25, not Applicant's burden to show that it does not inherently disclose the claimed method.

The only remaining issue is whether Wagner et al. teaches or suggests modifying the method disclosed in Luks et al. in order to meet every limitation in claim 25. As discussed

above, Wagner et al. discloses a sacral screw used to affix a spinal rod to a person's vertebrae. As such, Wagner et al. is completely irrelevant to the issue of fixation of a soft tissue graft within a bone tunnel using an interference screw. For this reason, even if Luks et al. and Wagner et al. were combined, the combined teachings would not teach or suggest every limitation contained in method claim 25. Moreover, the method in Luks et al. could not be modified to use the sacral screw of Wagner et al. since the sacral screw would be completely unsuitable for use as an interference screw, *e.g.*, because it includes an enlarged head made of steel or titanium that would stick out from the bone tunnel if used and/or because Luks et al. requires a screw made of bone rather than metal. In view of the foregoing, Applicants submit that claim 25 is patentable over the art of record.

Independent claims 1, 17, 21, 24, and 29 have been amended to emphasize that the claimed interference screws are designed for "cortical and cancellous bone fixation of a soft tissue graft within a bone tunnel", more particularly that the "proximal threaded section" is "for cortical bone fixation" (claim 1) or "configured so as to lie primarily adjacent to cortical bone" (claims 17, 21, 24, and 29). Similarly, the distal threaded section is "for cancellous bone fixation" (claim 1) or "configured so as to lie primarily adjacent to cancellous bone" (claim 17, 21, 24, and 29). The foregoing emphasizes that different portions of the interference screw are designed to provide cortical bone fixation and cancellous bone fixation, respectively.

As discussed above, the interference screw is designed so as to provide a greater fixation force in the cortical bone region and a lesser fixation force in the cancellous bone region. This is accomplished by providing an interference screw in which the distal threaded section has a diameter that is less than the diameter of the proximal threaded section. The greater diameter of the proximal threaded section provides greater fixation force in the cortical bone region and in the smaller diameter of the distal threaded section provides for a lesser fixation force in the cancellous bone region.

In addition to the foregoing, each of independent claims 1, 17, 21, 24 and 29 has been amended to specify that "the distal threaded section ha[s] a length that is greater than the length of the proximal threaded section in order for the interference screw to apply force along a greater distance in the cancellous bone region compared to the cortical bone region". Support for this limitation is shown in the drawings, particularly Figures 1, 2, 5, 6 and 7. Because the claimed interference screw provides for lesser fixation of the soft tissue graft in the cancellous bone region in order to prevent damage to the soft tissue graft, this is compensated for by providing a

distal threaded section having a greater length than the proximal threaded section. That is, whereas the interference screw has a smaller diameter in the cancellous bone region in order to apply less average force per thread against the soft tissue graft, the overall force in the cancellous bone region is enhanced by the increased length of the screw in the cancellous bone region. In this way, claims 1, 17, 21, 24 and 29 recite an interference screw that is specifically designed to strike the correct balance between strong initial fixation of the soft tissue graft while preventing undue damage to the soft tissue graft. Strong initial fixation helps prevent pull-out or substantial loosening of the graft before the graft and bone have had a chance to heal and grow together. On the other hand, protecting the soft tissue graft from undue damage enhances long-term joint stability by ensuring a strong, permanent living tissue graft over time.

None of the cited references teach or suggest an interference screw designed so as to strike the correct balance between strong initial fixation of the soft tissue graft while preventing undue damage to the soft tissue graft in the manner provided by the interference screws defined in claims 1, 17, 21, 24 and 29.

Miller discloses a compound screw that is specifically designed to be driven into "unbored wooden material . . . by means of hammer blows, or the like, until the thread 5 begins to enter the wood". Col. 1, lines 50-55. As such, not only is Miller completely unconcerned with interference fixation of a soft tissue graft, Miller provides design features so as to yield a screw that is uniquely suitable for being hammered into "unbored wooden material". Moreover, inspection of the drawings indicates that Miller neither teaches nor suggests a screw that includes a "distal threaded section having a length that is greater than the length of the proximal threaded section in order for the interference screw to apply force along the greater distance in the cancellous bone region compared to the cortical bone region". Whereas there is no indication that the compound screw of Miller has the correct size or shape so as to be suitable for interference fixation of a soft tissue graft, even if one were to use the screw of Miller in a manner not intended, the result would be very different from the interference screw cited in claims 1, 17, 21, 24 and 29. The compound screws illustrated in Figures 1-3, to the extent they include any structure that is analogous to the proximal and distal threaded sections, do not include a distal threaded section "having a length that is greater than the length of the proximal threaded section". Indeed, the proximal threaded section, to the extent one exists, is considerably longer than the distal threaded section in the embodiments shown in Figures 1-3. Figure 4, on the other hand, discloses an embodiment in which the proximal and distal threaded sections appear to have

the exact same length. As plainly shown in Figure 4, the upper threaded portion 2''' is interconnected with a lower threaded portion 4''' by means of an angled transition portion 6'''. Counting the number of threads in the upper versus lower threaded portions shows that the upper portion 2''' includes five threads on the left side and six threads on the right side. Lower threaded portion 4 also includes five threads on the left side and six threads on the right side. As such, upper threaded portion 2''' and lower threaded portion 4''' have the exact same length. Therefore, Miller does not teach or suggest every limitation contained in claim 1.

The only remaining issue is whether Rieser et al. teaches or suggests an interference screw in which the distal threaded section has "a length that is greater than the length of the proximal threaded section". In fact, Rieser et al. discloses interference screws used for bicortical fixation that have substantially constant diameter along most of their length and a taper towards the tip. To the extent that the Rieser et al. screws have a "distal threaded section" it clearly does not have a "length that is greater than the length of the proximal threaded section". Accordingly, the combination of Miller and Rieser et al. neither teaches nor suggests every limitation of claims 1, 17, 21, 24 and 29 for at least this reason.

Moreover, independent claim 1 further recites a "proximal end having an angle relative to the central axis in a range of about 10° to about 80°". For the reasons discussed above, it would be contrary to Miller et al. to provide a screw having an angled proximal end. Since the compound screw of Miller is specifically designed to be driven into "unbored wooden material . . . by means of hammer blows, or the like" (col. 1, lines 50-55), but because providing a proximal angled end would greatly inhibit or prevent the ability of a screw to be hammered into wood, one of skill in the art would not have been motivated to modify the screw contained in Miller because to do so would render the Miller screw unsatisfactory for its intended purpose. *See* MPEP § 2143.01. For this additional reason, Applicant believes that claim 1 is patentable over the prior art of record.

Claim 21 further recites "a recess, extending through the threaded body from the proximal end at least partially toward the distal end that is sized and configured to receive at least a portion of the drive shaft of a driver". Miller neither teaches nor suggests any such structure. Instead, Miller shows a common screw head having a single slot to receive a flathead screwdriver. No other means for receiving a driver are disclosed in Miller. Moreover, for the reasons set forth above, one of skill in the art would not have been motivated to combine Rieser et al. with Miller. As a result, whatever features are disclosed in Rieser et al. are irrelevant

relative to the technical problem being solved by Miller such that one of skill in the art would not have been motivated to modify Miller according to Rieser et al. For this additional reason, claim 21 is believed to be patentable over the prior art of record.

New dependent claim 33 further recites a method in which the interference screw is "at least one of poly-*l*-lactic acid, titanium, or stainless steel". Luks et al., in contrast, require the use of an interference screw made from bone and disparages the use of polymers and metals. As such, Luks et al. teaches away from the use of an interference screw as recited in new claim 33.

Finally, new independent claim 34 alternatively recites an interference screw having proximal and distal threaded sections in which the "distal threaded section ha[s] a constant diameter that is less than the average diameter of the proximal threaded section" as well as a "proximal end terminating said proximal threaded section having an angle relative to the central axis and arranged from about 10° to about 80°". As discussed above relative to claim 1, it would be contrary to the teachings of Miller to provide a screw having an angled proximal end, especially one having an angle up to about 80°, since an angled proximal end would render the Miller screw unsatisfactory for its intended purpose. *See* MPEP 2143.01. For at least this reason, claim 34 is believed to be patentable over the prior art of record.

D. Comparative Study

During the Examiner Interview, a comparative study conducted by a third party that compared an interference screw within the scope of the claims of the present application was compared with an interference screw within the scope of the claims of Rieser et al. A copy of that study is attached hereto as Exhibit A. According to the study, a 35-mm BioScrew XtraLok sold by Linvatec of Largo, Florida was compared with a "doubled tibialis interior graft-intibial tunnel fixation using retrograde bioabsorbable interference screw" made by Arthrex, of Naples, Florida. As evidence that the tested BioScrew XtraLok device falls in the scope of the present claims, Applicant attaches hereto as Exhibit B a spec drawing of the BioScrew" tapered screw having a length of 35 mm. As seen in the drawing at Exhibit B, the BioScrew is virtually identical to the interference screw depicted at Figure 2 of the present application. As evidence that the Arthrex screw tested is the same as what is claimed in Rieser et al., Applicant notes that the Rieser et al. patent is assigned to Arthrex, Inc., and that it describes bi-cortical tibial fixation (*i.e.*, "doubled tibialis . . . fixation"). The Arthrex screw is referred to as the "Retrograde" screw or the "RetroScrew".

According to this third-party study, the results of which are available to the general public for review, analysis and comment, "[m]aximum load at failure after cyclic loading for the RetroScrew was 778.7 ± 177.5 N". In contrast, "[m]aximum load at failure after cyclic loading for the BioScrew XtraLok screw was 1436.3 ± 331.3 N". Exhibit A, pp. 1-2. This study concluded that "[f]ixation using XtraLok screws displayed greater maximum load at failure than RetroScrew fixation . . . as well as greater stiffness". The paper further concluded that "[f]ixation using a single 35-mm BioScrew XtraLok screw displayed increased maximum load at failure and stiffness compared with the 20-mm RetroScrew with 17-mm cortical back-up fixation". Exhibit A, p. 2.

The foregoing constitutes evidence of nonobviousness of the claims, since the BioScrew XtraLok screw that was tested falls within the scope of every claim in the present application and showed far superior results compared to the screw claimed in the Rieser et al. patent. In fact, even if one were to contend that the RetroScrew was not the same as the bicortical fixation device of Rieser et al., the fact remains that a 35-mm screw according ot the invention provided far better fixation than the combined length of 2 screws (37 mm) in the RetroScrew method. That 35 mm of contact provides far better fixation than 37 mm of contact is a surprising and unexpected result in and of itself.

III. CONCLUSION

In view of the foregoing, Applicant believes that the claims are presently in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application, may be clarified through a telephone interview or that can be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 20th day of August 2004.

Respectfully submitted,

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EXHIBIT A

Biomechanical Testing of Tibialis Anterior Graft Tibial Tunnel Fixation with Bioabsorbable RetroScrews and BioScrew XtraLok in Porcine Bones

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Purpose: This study evaluated the failure mode, maximum load at failure, displacement at failure, and stiffness differences of doubled tibialis anterior graft-tibial tunnel fixation using retrograde bioabsorbable interference screws (Arthrex, Naples, FL) and 35-mm BioScrew XtraLok (Linvatec, Largo, FL) after cyclical loading.

Type of Study: Experimental laboratory biomechanical study.

Hypothesis: There is no difference in maximum load, displacement and stiffness at failure of doubled tibialis anterior graft-tibial tunnel fixation using Retrograde (Arthrex, Naples, FL) and 35-mm BioScrew XtraLok (Linvatec, Largo, FL) after cyclical loading.

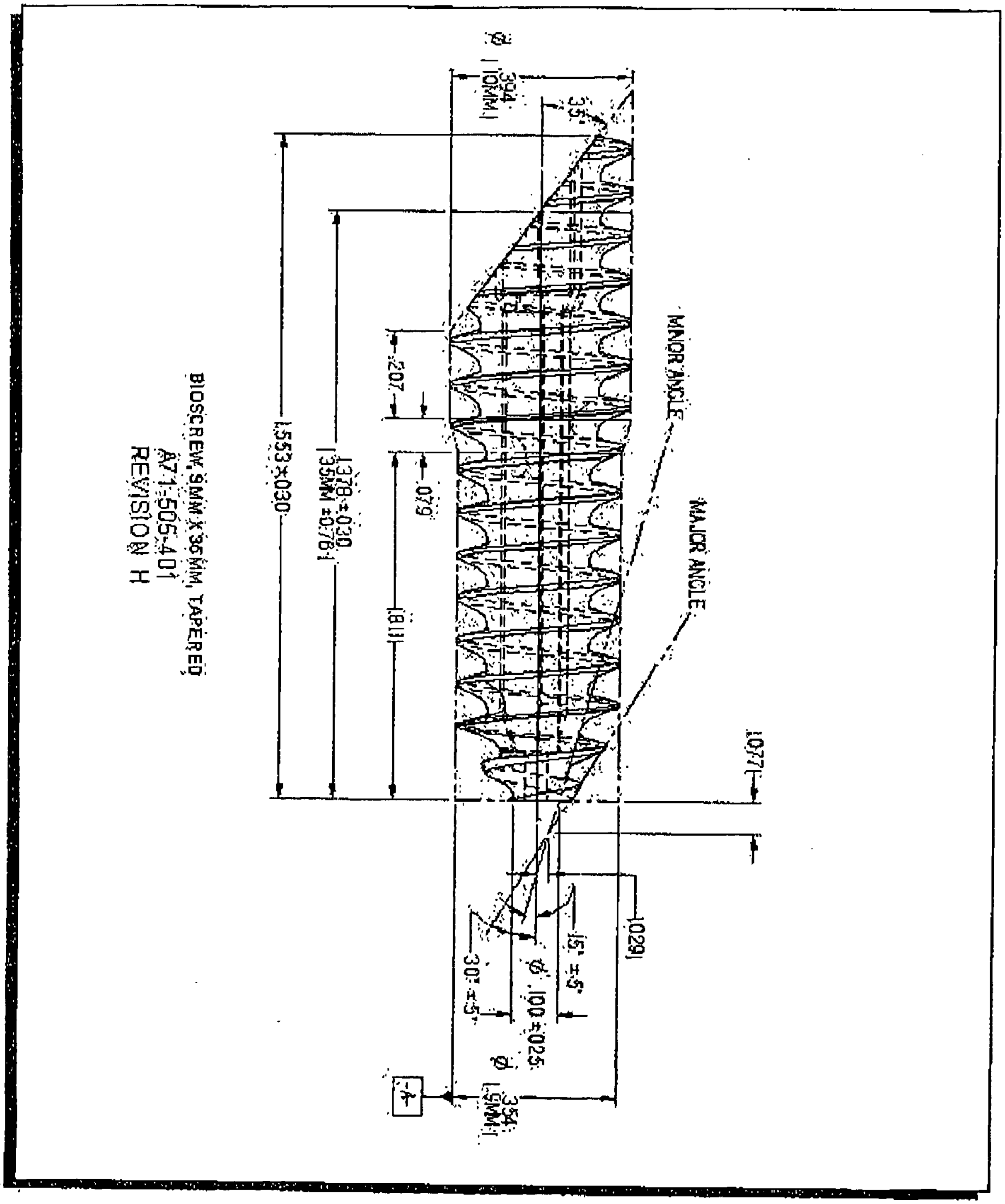
Methods: Twelve specimens of porcine tibias were divided into 6 matched pairs based on bone mineral densitometry. Wilcoxon tests comparisons were used to assess group differences ($P < .05$).

Results: Maximum load at failure after cyclic loading for the RetroScrew was 778.7 ± 177.5 N, with a displacement of 5.3 ± 2 mm and a stiffness modulus of 204.3 ± 52.9 N/mm. Maximum load at failure after cyclic loading for the BioScrew-XtraLok screw

was 1436.3 ± 331.3 N, with a displacement of 5.9 ± 2.6 mm and a stiffness modulus of 323.6 ± 56.8 N/mm. Fixation using XtraLok screws displayed greater maximum load at failure than RetroScrew fixation ($P = .028$) as well as greater stiffness ($P=0.046$). Significant differences were not evident for displacement at final pullout. All constructs failed by graft pullout.

Conclusions: Fixation using a single 35-mm BioScrew XtraLok screw displayed increased maximum load at failure and stiffness compared with the 20-mm RetroScrew with 17-mm cortical backup fixation.

EXHIBIT B


BIOSCREW, 9MM X 35MM, TAPERED
A71-505-401
REVISION H
MAJOR ANGLE
MINOR ANGLE
1.553±.030
1.378±.030
(35MM ±.076)
.207
.079
.029
15° ±5°
30° ±5°
Ø .100±.025
-A-